**THYROFLEX 3G INSTRUCTION MANUAL**

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NiTek Medical, Inc.
THYROFLEX 3G INSTRUCTION MANUAL

Section 1: Hardware Included

1. Debun-Linux XUbuntu Netbook with Thyroflex3G software preloaded.
2. USB reflex hammer system with USB link stick and hand sensor band.
3. Additional blue reflex hammer to assist in locating the reflex muscle.
4. Power cord (adaptor, if necessary, depending on country).
5. Symptoms Sheet.
7. List of compatible printers.
8. USB memory stick.

Note: All programs on this computer will require only a single click. Double clicking will duplicate the launch of multiple screens. Please allow at least 30 seconds for system to launch or change between screens. If a screen does not show up after 30 seconds or appears to be stuck, press “Fn, Alt, F4” key on the keyboard all at once to populate the hidden screen already open behind the current screen or to go back to the desktop once in the Thyroflex3G program.
Section 2: Computer Set-Up

1. Turn on the computer using the small rectangular blue power button located in the top right hand corner.

2. Accept the terms and conditions of use of device.

3. To set up the wireless Internet connection, go to “Config” and “Network Manager” icon. Select the wireless Internet connection. It may be necessary to enter in your Internet service provider ID and password to establish password protected connections. DISCLAIMER: Nitek is not responsible for understanding your specific Internet type. Our computers are designed to connect to wireless Internet connections or CAT cable connections. If you are unable to connect through the suggestions from our manual or video please consult your IT professional or Internet provider.

Note: If screen does not populate, press “Fn, Alt, F4” key on the keyboard all at once to show hidden screen during Internet set or to go back to the previous screens or desktop once in the Thyroflex program.

Important! : Internet connection is essential to obtaining calculated test results and tracking of monthly testing usage for billing purposes.
Configuration Main Screen: Set up Internet Connection.

To connect to the Internet, locate the arrows in the top bar. Click and a pull down menu will appear below.

4. **Connect to the Internet**
   The two arrows located in the top right hand side of the bar, are for the Internet connection.

   ![To Connect](image1)
   ![Connected](image2)

5. The pull down menu, as shown below, will pick up what services are available or within range. Select your WiFi and register with your password to authenticate.

   ![WiFi Connections](image3)

   *(This is just a sample of WiFi connections)*
6. If you briefly lose Internet connection during testing, you will still be able to complete your test and obtain results. However, you will only be able to test up to 10 “off-line” tests without the Internet before you will be locked out of the system from any further testing. The following error message will appear.

Loss of Internet Connection Error Message While Going To Test = Not On Internet, Therefore, Connect To The Internet ASAP.
7. Connect the USB Stick to a port on the computer and check for the RED light.

Note: Each Thyroflex has matched ID #'s on the hammer link box and a PAC ID # on the top right hand corner of the rotating body patient input screen. These numbers are unique to your device. Every test can be seen in real time on the NiTek server. If you need assistant with placing marker on a graph or with test result interpretation or simply want us to review your graphs during your training period, email us at support@nitekmedical.com.

Section 3: Testing

1. Launch the NiTek 3G software from the desktop “Nitek Software” icon. Remember to single click and watch for rotating clock.
The PAC I.D. number is the unique identifier for your Thyroflex G3 and is synced to the Nitek server.

2. At the main menu, click on the drop down menu under “Physician” and select “Edit Physicians” to manage your physician database.

3. Select “Add New” and type in the new physician’s name or select the appropriate physician name and click “Done”.

4. To add a new patient, click on the drop down menu under the “Patient” button, select “New Patient.”

5. Select the “Thyroflex Brachial Radialis” button to enter in patient information.
Section 4: Patient Record

1. Use the “Tab” key to go through the fields, fill in the patient name, birthday, gender, height, and weight.

2. Click on the drop down arrow to select the “sex”.

Note: Height and weight unit of measurement is preset for your region.

![Patient Information Screen](image.png)
3. If patient is on thyroid therapy, click on the drop down menu to select their current thyroid medication and dosage level.

4. Enter in patient “Hyper” and “Hypo” Thyroid Symptom Survey Score from their symptoms survey sheet.

5. Enter the following codes “FBD” for fibrocystic breast disease and lumps in breast. Uterine fibroids should be “UF” or ovarian cysts “OC” and prostate is “P.” If the patient does not have any of the above listed then enter “No.”

6. Press “Run Test” to begin testing.
Section 5: Patient Preparation

Patient arm position & band placement

1. Patient should be seated comfortably in the chair with back fully supported by the backrest and both foot planted firmly on the ground (chair pulled close to table). Do not cross legs.

   **Note:** Patient crossing their legs or feet during testing will affect their test result.

2. Patient’s arm should be fully supported on a tabletop and their wrist hanging over the edge of the armrest.

3. Ask the patient to make a letter “L” with their thumb. Slip the band over the four digits leaving the thumb out and stopping at the crease of the thumb. Align the sensor on the blue band directly over the middle finger knuckles with the wire running down the middle finger.

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**Belly of Extensor Digitorium Muscle**

**Extensor Digitorium Anatomy**
4. The Thyroflex tests the reflex of the Brachioradialis muscle (which sits directly under the Extensor Digitorium muscle); therefore, consistency and accuracy of the test is dependent on finding and hitting this correct muscle.

5. **This is the most critical part of the test.** To locate this muscle and mark it for ease of testing, have patient dorsiflex their hand, straighten all fingers out, hold, and have the patient wiggle the middle finger only. Locate the muscle group that is moving (distal to the elbow crease on the forearm and approximately two to three fingers down) and mark the muscle with an “x.”

6. Always utilize the blue reflex hammer provided to strike and to test the muscle reflex. If the correct muscle has been marked, the patient will have a strong middle finger reflex. If patient wrist reflex sideways, use the blue reflex hammer to hit a little bit over to the right or left of the mark on the forearm until patient display a strong middle finger reflex. Remark that spot. If you get the middle finger to fire, you are ready to proceed with the test. Do not test unless the middle finger fires.
Section 6: Performing Reflex Test

1. Cock the hammer by pushing up on the plunger until you hear a click. Place hammer with plunger perpendicular over the mark on the arm and depressed hammer slightly into the arm until skin indents to hold the hammer firmly in place over the muscle.

   Note: The pad is not necessary, but if patient complains of discomfort with the force of the hammer, you may place a pad over the patient’s arm to test.

   Push up on plunger to cock hammer.

   Place hammer perpendicular to muscle.

   If needed, use pad over arm if patient complains of discomfort from hammer.

2. Patient needs to be completely relaxed with wrist dependent over the edge of the armrest and both feet planted firmly on the ground. To obtain a better reflex from patient, have patient make eye contact with you and use distraction techniques (asking patient to count backwards from 100 in serial sevens or say the ages of their children, etc.) right before the hammer is triggered.
3. Re-cock the hammer and test patient reflexes until you have obtained 3 good reflexes. You can test up to 5 times, but it is not necessary.

Section 7: Marker Placement

There is a connectivity button on the bottom right hand corner of the screen called “Device” and “Server.” If the USB of the hammer and linkbox are not connected then it will show in red, “No Device” or, if it is connected it will show in green “Device.” If you are connected to the Internet it will show “Server” in green. If you are not connected to the Internet it will show “No Server” in red.

1. The Thyroflex will automatically set the reflex markers for you on valid reflex result (see graph 1-3).

2. Invalid test results will be indicated by the RED highlight (see graph 5) and will need to be cleared. Hit “Clear” so not to be included in the calculation of the results.

   Note: Graph 4. Hand sensor on upside Down (Wire running up the hand.)
Graph # 2 & # 3: Fire marker (Green) is misplaced and will need to be re-adjusted to the left and right as indicated. (Click on the file to activate – the fire button will brighten up.)

3. Manual adjustment to the markers needs to be made when the “Fire” marker is not correctly set by the system at the trough (lowest point) of the bottom of the bell curve. Click on the Fire or Pre-fire button to change line placement.

4. On the bottom right hand corner, the red and green bars should be approximately the same length. As shown in graph 3, the green bar is too short. Either the green fire marker line should be moved or the test cleared.
5. Clearing incorrect results:
   If you do not like the look of the test results (Bell Curves) in the above photo (note that the bars on the right side are not equal) hit the clear button to clear out tests you do not want.

   In the example above in graph #3, the Bell Curve did not quite come down to the bottom line. The fire marker can also be manually placed, by tracing the descending Bell Curve top 1/3 of the line to where it would have crossed the base line.

   **Graph # 1, 2 and 3: Perfect marker placement**

6. Look at the “Value Comparison” bars. All the red “Pre-fire” and all the green “Fire” bars should be relatively the same length. If bars are uneven, re-check the placement of the markers.

7. Click on **“Results”** to obtain result summary page as shown below.
8. The blank box next to the RMR result allows you to add any special notes into the patient’s charts. Click on the drop down arrow menu to add new text.

9. Press “Done” to save test result locally on the system. (Screen returns to patient input page.)

10. Press “Retest” to immediately retest the same patient.

11. Press “Print” to print and/or save a PDF file version of the test report to a USB memory stick. See section 11 for further instructions.
Section 8: Result Interpretation

<table>
<thead>
<tr>
<th>Condition</th>
<th>Time Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hyperthyroidism</td>
<td>≤ 51 ms</td>
</tr>
<tr>
<td>Normal Range</td>
<td>52-136 ms</td>
</tr>
<tr>
<td><strong>Green</strong> (Optimal)</td>
<td>52-100 ms</td>
</tr>
<tr>
<td><strong>Yellow</strong> (Herbal Supplement)</td>
<td>101-119 ms</td>
</tr>
<tr>
<td><strong>Orange</strong> (Borderline)</td>
<td>120-136 ms</td>
</tr>
<tr>
<td><strong>Red</strong> Hypothyroidism (Use prescription Meds)</td>
<td>≥137 ms</td>
</tr>
</tbody>
</table>

1. Take note of the “Reflex” time. Normal range is 52-136 ms

2. Optimal reflex time is 52-100 ms with the purple bar graph falling in the **green** zone.

3. Treat patient with herbal supplement when reflex time is 101-119 ms with the purple bar graph falling in the **yellow** zone.

4. Borderline reflex time is 120-136 ms with the purple bar graph falling in the **orange** zone.

5. Treat patient with prescription medication when patient
   - “Hypo” symptoms is ≥8
   - RMR is 2,250 for the average fit female and 2,750 for the average fit male (the average person burns 109 calories per hour at rest) and/or their RMR is 400 calories less per day then the average person. Factor in ± 250 calories for an over/under weight or aged patient.
   - Reflex time is ≥136 ms with the purple bar graph falling in the **red** zone.

6. ARNICA: We recommend that Arnica is used to take away any bruising on the patient arm.

7. HASHIMOTO’S & GRAVES: If the patient has both 12+ on the Hypo side of the symptom survey and 7+ on the Hyper side, and it includes Tachycardia and/or Palpitations. We recommend that an antibodies test is run for Hashimoto’s and Graves.
Section 9: Retesting Patient

1. It is recommended to retest and titrate patient after 30 days to allow the body to equilibrate to the thyroid medication. To retest a patient, select database from the “Physician” drop down menu, select patient name from the “Patient” drop down menu, and select “Thyroflex Brachial Radius” click new test and modify patient information, if necessary.

2. After selecting the patient for retest, you can view the patient’s past tests by highlighting the last test you want to view. Then click on details.
3. Patient previously on medication will likely have a weight and symptom change; therefore, remember to update patient “Weight”, “Medications”, and “Symptoms” information.

4. Then click “Run Test”.

Section 10: Viewing Patient Test History

Patient Test History at a Glance

1. To view patient's testing history, dosage, and symptom, pull up patient information as you would for a re-test, highlight the test date, and click on “Details” to view or print the patient report.
Section 11: Printing and Saving Thyroflex Instructions

Please note for printing: Your printer must be compatible with your machine. Please view this site to make sure your printer is compatible: http://linuxdeal.com/printers.php

1. Open up client’s report.
2. Left click on “Details” button once.

3. “JasperViewer” will pop up.
4. Left click on the “Print” button once.

5. “Name” should be set already as “PDF.”
6. Click on the “Print” button.
To “Save” as a .pdf file to documents folder or to your flash drive/memory stick:

1. Insert memory stick and wait for it to load.
2. Drag the screen that pops up to the side of your desktop.
3. Left click on “Print” button.
4. “Jasperview” will pop up.
5. Left click on the “Save” button once.

6. In the “Save In” area, if “Nitek” is not showing, use the scroll down arrow to find it.
7. Under “File Name” type your client’s name there.
8. Under “Files of Type” use the scroll down arrow until you find “PDF.”
9. In the middle section, left click once on “Documents.” That is where your .pdf file will be saved to.
10. Left click on the “Open” button once.
11. Another screen will open, left click on the “Save” button once. Your .pdf is now saved in your “Documents” folder.
12. Close out of the “JasperViewer” and the client’s report.
13. Next, hover your mouse over the upper left hand side of screen and click on the blue icon, Accessories, and then File Manager.

14. With the “File Manager” open, browse the left hand side of the screen. Look for “Documents.” Left click on that folder once. In the “Documents” folder you will find your .pdf that you just saved.
The following steps are for moving the .pdf report to your memory stick.

1. In the “Documents” folder, left click your mouse on your .pdf and move the report to your memory stick, just drag it over to the left hand side of the screen to your memory stick. A copy will still be in your “Documents” folder.

2. When you are done moving your reports to the memory stick, you can close the “File Manager.”

To safely remove your memory stick:

1. Right click on your memory stick on your desktop. Left click on “Eject Volume.” Remove your memory stick from the machine.
2. You can now take your memory stick to another computer and print your reports.
Section 12: Technical Support

If you have questions, click on the “?” button for support contact information.

How to contact Nitek, if help is needed.

If more than one screen is open it will show in the top bar.

“i” equals the number of tests left.

When your tests get too low, the Thyroflex will automatically download as long as you are online, the new tests, seemlessly and automatically load additional tests onto your computer. If your computer is offline, the following message will show up.
Make sure your Thyroflex is **online**, so the Nitek server can seamlessly sync your new test.

To turn your Thyroflex G3 off, go to “**Nitek**” on the top bar and click on **shut down**.
Contact listing:

Billing: Mitzi
mitzi@sierraaccountingservices.com

Training: Betty
bjmcelligottnitkmedical@gmail.com

Clinical Questions: Dr. Turner
drturner@nitkmedical.com

Pharma: Anushka
anushka@nitkmedical.com

Admin: Jason
Jason@nitkmedical.com

Consulting Doctor: Dr. Noemi Q
drnoemiq@gmail.com
THYROID (Iodine/Adrenal) SYMPTOM SURVEY

PATIENT NAME: _____________________
DOB: _____________________
Date: _____________________

I understand that the Thyroflex™ uses a reflex hammer that may leave a bruise, as such; I will not hold the Practitioner or Nitek Medical Inc. responsible for such injury. __________ Initial here

Do you suffer from any of the following?

Rate your symptoms below from a scale of: 0 to 3 (0= None, 1= Mild, 2= Moderate, 3= Severe)

Thyroid
6. _____ Tiredness & Sluggishness, lethargic
7. _____ Dry Hair or Skin (Thick, dry, scaly)
8. _____ Sleep More Than Usual
9. _____ Weaker Muscles
10. _____ Constant Feeling of cold (fingers / hands/ feet)
11. _____ Frequent Muscle Cramps
12. _____ Poorer Memory
13. _____ More Depressed (mood Change easily)
14. _____ Slower Thinking
15. _____ Puffier Eyes
16. _____ Difficulty with Math
17. _____ Hoarse or Deeper Voice
18. _____ Constipation
19. _____ Coarse Hair / Hair loss / brittle
20. _____ Muscle / Joint Pain
21. _____ Low Sex Drive / Impotence
22. _____ Puffy Hands and Feet
23. _____ Unsteady Gait (bump into things)
24. _____ Gain Weight Easy
25. _____ Outer Third Of Eyebrows Thin
26. _____ Menses More Irregular (should be 28 Days)
27. _____ Heavier Menses (clotting / 3+ days)
28. _____ Carpel Tunnel Syndrome

Total HYPO Score (8)

29. _____ Palpitations (Skipping of heart beat)
30. _____ Insomnia
31. _____ Tachycardia (Rapid or irregular heart beat)
32. _____ Shakiness
33. _____ Increased Sweating
34. _____ Brittle Nails
35. _____ Loss of Appetite

Total HYPER Score (0)

DHEA
• _____ Constantly exhausted & tired
• _____ Can not tolerate noise
• _____ My Libido is low
• _____ Muscles are getting flabby (Loosing muscle tone)

Total DHEA (2)

Adrenals (Cortisol)
• _____ Rapid heart beat
• _____ I’m stressed out
• _____ Have eczema, psoriasis, skin allergies, rashes
• _____ Digestive problems
• _____ Easily confused
• _____ Wake up tired (The following 6xQ’s are: Y=1, N=0)
• _____ Wake up full of energy Y/N
• _____ 2 to 4 pm feel tired, seek snack/Tea/Coffee/Coke Y/N
• _____ Fall asleep in front of TV/reading/computer(before bed) Y/N
• _____ As soon as I go to bed - Drop straight to sleep Y/N
• _____ Need to read/TV -10 to 15 mins to drift into sleep Y/N

Total Adrenal (3)

Iodine/Iodide
• _____ Fibrocystic Breast /lumps/ ovarian cysts
• _____ Goiter Bulge or Band Around the Neck
• _____ Slow Speech
• _____ Enlarged tongue
• _____ Puffy Face Puffy Hands

Total Iodine/Iodide Symptoms (0)

• _____ Do you use salt with iodine added Y=1, N=0
• _____ Number of days per week you eat seafood/shellfish

Total iodine In (6)* (Excludes Salmon/Tilapia/Trout/Fresh water fish)

Melatonin, Serotonin, Tryptophan
• _____ Upon waking feel tired
• _____ Wake up during the night
• _____ If awakening,( in middle of night), cannot get back to sleep
• _____ Trouble falling asleep
• _____ Use a sleep aid, or drink Alcohol to relax
• _____ My mind is busy when I want to sleep

Total Melatonin (2)

CoQ10
• _____ Do you have stamina Y=1, N=0

ACTH
• _____ Do you lack willpower & energy Y=1, N=0
• _____ Patches of hair loss Y=1, N=0
• _____ Pale complexion/sunburn easily Y=1, N=0
• _____ Often have Memory Loss Y=1, N=0

Total ACTH (2)

Check Here for: Antibodies Test = If: (Hypo = 12+, Hyper = 7+, Includes-Tachycardia and or Palpitations  Yes / No

TF.G3.V6.17.13  26
## Test Results:

**TREATMENT**

**Hypo/Hyper:** 8 / 0

**Thyroid:**

**Reflex Time:** Hyper = 52 = >Hypo = 136, (optimal 52-100) (B/L 120 – 136)

**Iodine/dide:**

**RMR:** Women=2,250 cal/day, Men=2,750 +/- 250 cal/day for over/underweight or aged

**Adrenal**

**RMR:** Will show a reading of about 400 calories below baseline (before treatment)

**DHEA**

**VitD**

**CoQ10**

**ACTH**

**Adre**

**Mela**

**5HTP**

**Other**

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### Manifestation of Misdiagnosed Hypothyroidism:

- **Neurological symptoms**
  - Headache •
  - Paresthesias •
  - Cerebellar ataxia (incoordination) •
  - Deafness (nerve or conduction) •
  - Vertigo or Tinnitus (ringing in the ear) •

- **Cognitive Deficits**
  - Calculation, memory, reduced attention span •
  - Sleep apnea •

**Total ACTH (2)**

### Myxedema coms •

- Psychiatric Syndromes •
- Schizoid or affective psychoses •
- Bipolar disorders •

**Skeletal System**

- Arthritis (joint stiffness) •
- Joint Effusions & Pseudogout •
- Carpal Tunnel Syndrome •

**Other Risks**

- Essential Hypertension •
- Difficulty swallowing •
- Polymyalgia •

**Sudden Death •**

- High or Low blood pressure •
- High Cholesterol & other blood fats •
- Vascular (blood vessel) Disease •
- Diabetes •
- Neurological (Parkinson's like diseases) •
- Double Alzheimer's Risk •
- Arthritis and inflammatory diseases •
- Miscarriage & Premature birth •
- Pregnancy Complications & birth defects •
Hashimoto’s Thyroiditis Protocol

- When the patient fills out the symptom survey, and the Hypo score is 12+, and the Hyper Score is 7+ and if the 7+ Hyper score includes Tachycardia and or Palpitations, we would suggest that there may be a immune problem.

- Ask the Patient when, where, and how often, the Tachycardia and or Palpitations occur, to rule out if they are Cortisol related.

- If they are not cortisol related, then we would suggest that an Antibodies test is ordered for Hashimotos and Graves, with a blood draw.

- Do not dose the patient at this time, until you get the results of the tests back.

- If the patient is Hashimotos, we would suggest the following:

  1. Start the patient on 100 mcg (or what you are comfortable with) Synthetic T4.
  2. The patient will feel better (symptoms will improve) for about 2 to 6 weeks.
  3. The patient will suddenly feel worse than before (symptoms increase).
  4. Switch the Patient overnight to 1 grain of Desiccated Natural Thyroid.
  5. Titrate the patient to the correct dose of Thyroid every 30 days.
  6. Always check the Iodine levels, dose with 12.5 mg of Iodine/Iodide if required.
  7. Check to see if the patient's cortisol levels are normal, take appropriate action.
  8. Results, in most patients, the Hypo symptoms will go below 8, the Hyper Symptoms will drop to below 3, the patient will feel a weight has been lifted off their shoulders.
  9. With this protocol, the antibodies will remain high, but the immune system is fooled, and will not attack the incoming medications.
  10. After about 1 ½ years to 2 years, the immune system will identify the incoming medications, as foreign, and the symptoms will return.
  11. At this stage, you switch the patient over to Synthetic T4 only.
  12. This will hold the immune response at bay for another 1 ½ years to 2 years.
  13. You then manage the patient for the rest of their life, switching between Synthetic and Desiccated.
  14. We have experienced excellent success with this protocol.
NP Thyroid (thyroid tablets, USP) — Bio-throid

CLINICAL PHARMACOLOGY: The steps in the synthesis of the thyroid hormones are controlled by thyrotrpin (Thyroid Stimulating Hormone, TSH) secreted by the anterior pituitary. This hormone’s secretion is in turn controlled by a feedback mechanism effected by the thyroid hormones themselves and by thyrotropin releasing hormone (TRH), a tripeptide of hypothalamic origin. Endogenous thyroid hormone secretion is suppressed when exogenous thyroid hormones are administered to euthyroid individuals in excess of the normal gland’s secretion. The mechanisms by which thyroid hormones exert their physiologic action are not well understood. These hormones enhance oxygen consumption by most tissues of the body, increase the basal metabolic rate, and the metabolism of carbohydrates, lipids, and proteins. Thus, they exert a profound influence on every organ system in the body and are of particular importance in the development of the central nervous system. The normal thyroid gland contains approximately 200 mcg of levothyroxine (T4) per gram of gland, and 15 mcg of liothyronine (T3) per gram. The ratio of these two hormones in the circulation does not represent the ratio in the thyroid gland, since about 80 percent of peripheral triiodothyronine comes from monodeiodination of levothyroxine. Peripheral monodeiodination of levothyroxine at the 5 position (inner ring) also results in the formation of reverse triiodothyronine (T3), which is calorigenically inactive. Triiodothyronine (T3) levels are low in the fetus and newborn, in old age, in chronic caloric deprivation, hepatic cirrhosis, renal failure, surgical stress, and chronic illnesses representing what has been called the “T3 thyronine syndrome.”

Pharmacokinetics – Animal studies have shown that T4 is only partially absorbed from the gastro-intestinal tract. The degree of absorption is dependent on the vehicle used for its administration and by the character of the intestinal contents, the intestinal flora, including plasma protein, and soluble dietary factors, all of which bind thyroid and thereby make it unavailable for diffusion. Only 41 percent is absorbed when given in a gelatin capsule as opposed to a 74 percent absorption when given with an albumin carrier. Depending on other factors, absorption has varied from 48 to 79 percent of the administered dose. Fasting increases absorption. Malabsorption syndromes, as well as dietary factors, (children’s soybean formula, concomitant use of anionic exchange resins such as cholestyramine) cause excessive fecal loss. T3 is almost totally absorbed, 95 percent in 4 hours. The hormones contained in the natural preparations are absorbed in a manner similar to the synthetic hormones. More than 99 percent of circulating hormones are bound to serum proteins, including thyroid-binding globulin (TBG), thyroid-binding prealbumin (TBPA), and albumin (TBA), whose capacities and affinities vary for the hormones. The higher affinity of levothyroxine (T4) for both TBG and TBPA as compared to triiodothyronine (T3) partially explains the higher serum levels and longer half-life of the former hormone. Both protein-bound hormones exist in reverse equilibrium with minute amounts of free hormone, the latter accounting for the metabolic activity. Deiodination of levothyroxine (T4) occurs at a number of sites, including liver, kidney, and other tissues. The conjugated hormone, in the form of glucuronide or sulfate, is found in the bile and gut where it may complete an enterohepatic circulation. Eighty-five percent of levothyroxine (T4) metabolized daily is deiodinated.

INDICATIONS AND USAGE: NP Thyroid tablets (thyroid tablets, USP) are indicated: 1. As replacement or supplemental therapy in patients with hypothryoidism of any etiology, except transient hypothyroidism during the recovery phase of subacute thyroiditis. This category includes cretinism, myxedema, and ordinary hypothyroidism in patients of any age (children, adults, the elderly), or state (including pregnancy); primary hypothyroidism resulting from functional deficiency, primary atrophy, partial or total absence of thyroid gland, or the effects of surgery, radiation, or drugs, with or without the presence of goiter; and secondary (pituitary), or tertiary (hypothalamic) hypothyroidism (See WARNINGS). 2. As pituitary TSH suppressants, in the treatment or prevention of various types of euthyroid goiters, including thyroid nodules, subacute or chronic lymphocytic thyroiditis (Hashimoto’s), multinodular goiter, and in the management of thyroid cancer. 3. As diagnostic agents to differentiate suspected mild hyperthyroidism or thyroid gland autonomy.

CONTRAINDICATIONS: Thyroid hormone preparations are generally contraindicated in patients with diagnosed but as yet uncorrected adrenal cortical insufficiency, untreated thyrotoxicosis, and apparent hypersensitivity to any of their active or extraneous constituents. There is no well documented evidence from the literature, however, of true allergic or idiosyncratic reactions to thyroid hormone.

WARNINGS: Drugs with thyroid hormone activity, alone or together with other therapeutic agents, have been used for the treatment of obesity. In euthyroid patients, doses within the range of daily hormonal requirements are ineffective for weight reduction. Larger doses may produce serious or even life-threatening manifestations of toxicity, particularly when given in association with sympathomimetic amines such as those used for their anorectic effects. The use of thyroid hormones in the therapy of obesity, alone or combined with other drugs, is unjustified and has been shown to be ineffective. Neither is their use justified for the treatment of male or female infertility unless this condition is accompanied by hypothyroidism.

PRECAUTIONS: General — Thyroid hormones should be used with great caution in a number of circumstances where the integrity of the cardiovascular system, particularly the coronary arteries, is suspected. These include patients with angina pectoris or the elderly, in whom there is a greater likelihood of acute cardiac disease. In these patients therapy should be initiated with low doses, i.e., 15-30 mg NP Thyroid. When, in such patients, a euthyroid state can only be reached at the expense of an aggravation of the cardiovascular disease, thyroid hormone
dosage should be reduced. Thyroid hormone therapy in patients with concomitant diabetes mellitus or diabetes insipidus or adrenal cortical insufficiency aggravates the intensity of their symptoms. Appropriate adjustments of the various therapeutic measures directed at these concomitant endocrine diseases are required. The therapy of myxedema coma requires simultaneous administration of glucocorticoids (See DOSAGE AND ADMINISTRATION). Hypothyroidism decreases and hyperthyroidism increases the sensitivity to oral anticoagulants. Prothrombin time should be closely monitored in thyroid-treated patients on oral anticoagulants and dosage of the latter agents adjusted on the basis of frequent prothrombin time determinations. In infants, excessive doses of thyroid hormone preparations may produce craniostenosis.

Information for the Patient — Patients on thyroid hormone preparations and parents of children on thyroid therapy should be informed that: 1. Replacement therapy is to be taken essentially for life, with the exception of cases of transient hypothyroidism, usually associated with thyroiditis, and in those patients receiving a therapeutic trial of the drug. 2. They should immediately report during the course of therapy any signs or symptoms of thyroid hormone toxicity, e.g., chest pain, increased pulse rate, palpitations, excessive sweating, heat intolerance, nervousness, or any other unusual event. 3. In case of concomitant diabetes mellitus, the daily dosage of antidiabetic medication may need readjustment as thyroid hormone replacement is achieved. If thyroid medication is stopped, a downward readjustment of the dosage of insulin or oral hypoglycemic agent may be necessary to avoid hypoglycemia. At all times, close monitoring of urinary glucose levels is mandatory in such patients. 4. In case of concomitant oral anticoagulant therapy, the prothrombin time should be measured frequently to determine if the dosage of oral anticoagulants is to be readjusted. 5. Partial loss of hair may be experienced by children in the first few months of thyroid therapy, but this is usually a transient phenomenon and later recovery is usually the rule.

Laboratory Tests — Treatment of patients with thyroid hormones requires the periodic assessment of thyroid status by means of appropriate laboratory tests besides the full clinical evaluation. The TSH suppression test can be used to test the effectiveness of any thyroid preparation bearing in mind the relative insensitivity of the infant pituitary to the negative feedback effect of thyroid hormones. Serum T4 levels can be used to test the effectiveness of all thyroid medications except T3. When the total serum T4 is low but TSH is normal, a test specific to assess unbound (free) T4 levels is warranted. Specific measurements of T4 and T3 by competitive protein binding or radioimmunoassay are not influenced by blood levels of organic or inorganic iodine.

Drug Interactions — Oral Anticoagulants — Thyroid hormones appear to increase catabolism of vitamin K-dependent clotting factors. If oral anticoagulants are also being given, compensatory increases in clotting factor synthesis are impaired. Patients stabilized on oral anticoagulants who are found to require thyroid replacement therapy should be watched very closely when thyroid is started. If a patient is truly hypothyroid, it is likely that a reduction in anticoagulant dosage will be required. No special precautions appear to be necessary when oral anticoagulant therapy is begun in a patient already stabilized on maintenance thyroid replacement therapy.

Insulin or Oral Hypoglycemics — Initiating thyroid replacement therapy may cause increases in insulin or oral hypoglycemic requirements. The effects seen are poorly understood and depend upon a variety of factors such as dose and type of thyroid preparations and endocrine status of the patient. Patients receiving insulin or oral hypoglycemics should be closely watched during initiation of thyroid replacement therapy.

Cholestyramine — Cholestyramine binds both T4 and T3 in the intestine, thus impairing absorption of these thyroid hormones. In vitro studies indicate that the binding is not easily removed. Therefore four to five hours should elapse between administration of cholestyramine and thyroid hormones.

Estrogen, Oral Contraceptives — Estrogens tend to increase serum thyroxine-binding globulin (TBg). In a patient with a nonfunctioning thyroid gland who is receiving thyroid replacement therapy, free levothyroxine may be decreased when estrogens are started thus increasing thyroid requirements. However, if the patient’s thyroid gland has sufficient function, the decreased free thyroxine will result in a compensatory increase in thyroxine output by the thyroid. Therefore, patients without a functioning thyroid gland who are on thyroid replacement therapy may need to increase their thyroid dose if estrogens or estrogen-containing oral contraceptives are given.

Drug/Laboratory Test Interactions — The following drugs or moieties are known to interfere with laboratory tests performed in patients on thyroid hormone therapy: androgens, corticosteroids, estrogens, oral contraceptives containing estrogens, iodine-containing preparations, and the numerous preparations containing salicylates. 1. Changes in TBg concentration should be taken into consideration in the interpretation of T4 and T3 values. In such cases, the unbound (free) hormone should be measured. Pregnancy, estrogens, and estrogen-containing oral contraceptives increase TBg concentrations. TBg may also be increased during infectious hepatitis. Decreases in TBg concentrations are observed in nephrosis, acromegaly, and after androgen or corticosteroid therapy. Familial hyper- or hypothyroxine-binding-globulinemia has been described. The incidence of TBg deficiency approximates 1 in 9,000. The binding of levothyroxine by TBPA is inhibited by salicylates. 2. Medicinal or dietary iodine interferes with all in vivo tests of radio-iodine uptake, producing low uptakes which may not be relative of a true decrease in hormone synthesis. 3. The persistence of clinical and laboratory evidence of hypothyroidism in spite of adequate dosage replacement indicates either poor patient compliance, poor absorption, excessive fecal loss, or inactivity of the preparation. Intracellular resistance to thyroid hormone is quite rare.

Carcinogenesis, Mutagenesis, and Impairment of Fertility — A reportedly apparent association between prolonged thyroid therapy and breast cancer has not been confirmed and patients on thyroid for established indications should not discontinue therapy. No confirmatory long-term studies in animals have been performed to evaluate carcinogenic potential, mutagenicity, or impairment of fertility in either males or females.

Pregnancy — Category A — Thyroid hormones do not readily cross the placental barrier. The clinical experience to date does not indicate any adverse effect on fetuses when thyroid hormones are administered to pregnant women. On the basis of current knowledge, thyroid replacement therapy to hypothyroid women should not be discontinued during pregnancy.

Nursing Mothers — Minimal amounts of thyroid hormones are excreted in human milk. Thyroid is not associated with serious adverse reactions and does not have a known tumorigenic potential. However, caution should be exercised when thyroid is administered to a nursing woman.
Pediatric Use — Pregnant mothers provide little or no thyroid hormone to the fetus. The incidence of benefit from the small amounts of hormone crossing the placental barrier. Routine determinations of serum T4 and/or TSH is strongly advised in neonates in view of the deleterious effects of thyroid deficiency on growth and development. Treatment should be initiated immediately upon diagnosis, and maintained for life, unless transient hypothyroidism is suspected; in which case, therapy may be interrupted for 2 to 6 weeks after the age of 3 years to reassess the condition. Cessation of therapy is justified in patients who have maintained a normal TSH during those 2 to 6 weeks.

ADVERSE REACTIONS: Adverse reactions other than those indicative of hyperthyroidism because of therapeutic overdosage, either initially or during the maintenance period, are rare (See OVERDOSAGE).

OVERDOSAGE: Signs and Symptoms — Excessive doses of thyroid result in a hypermetabolic state resembling in every respect the condition of endogenous origin. The condition may be self-induced.

Treatment of Overdosage — Dosage should be reduced or therapy temporarily discontinued if signs and symptoms of overdosage appear. Treatment may be reinstalled at a lower dosage. In normal individuals, normal hypothalamic-pituitary-thyroid axis function is restored in 6 to 8 weeks after thyroid suppression. Treatment of acute massive thyroid hormone overdosage is aimed at reducing gastrointestinal absorption of the drugs and counteracting central and peripheral effects, mainly those of increased sympathetic activity. Vomiting may be induced initially if further gastrointestinal absorption can reasonably be prevented and barring contraindications such as coma, convulsions, or loss of the gagging reflex. Treatment is symptomatic and supportive. Oxygen may be administered and ventilation maintained. Cardiac glycosides may be indicated if congestive heart failure develops. Measures to control fever, hypoglycemia, or fluid loss should be instituted if needed. Antidrenergic agents, particularly propranolol, have been used advantageously in the treatment of increased sympathetic activity. Propranolol may be administered intravenously at a dosage of 1 to 3 mg, over a 10-minute period or orally, 80 to 160 mg/day, initially, especially when no contraindications exist for its use.

DOSE AND ADMINISTRATION: The dosage of thyroid hormones is determined by the indication and must in every case be individualized according to patient response and laboratory findings. Thyroid hormones are given orally. In acute, emergency conditions, injectable levothyroxine sodium may be given intravenously when oral administration is not feasible or desirable, as in the treatment of myxedema coma, or during total parenteral nutrition. Intramuscular administration is not advisable because of reported poor absorption.

Hypothyroidism — Therapy is usually instituted using low doses, with increments which depend on the cardiovascular status of the patient. The usual starting dose is 30 mg NP Thyroid, with increments of 15 mg every 2 to 3 weeks. A lower starting dosage, 15 mg/day, is recommended in patients with long-standing myxedema, particularly if cardiovascular impairment is suspected, in which case extreme caution is recommended. The appearance of angina is an indication for a reduction in dosage. Most patients require 60 to 120 mg/day. Failure to respond to doses of 180 mg suggests lack of compliance or malabsorption. Maintenance dosages 60 to 120 mg/day usually result in normal serum levothyroxine (T4) and triiodothyronine (T3) levels. Adequate therapy usually results in normal TSH and T4 levels after 2 to 3 weeks of therapy. Readjustment of thyroid hormone dosage should be made within the first four weeks of therapy, after proper clinical and laboratory evaluations, including serum levels of T4, bound and free, and TSH. T3 may be used in preference to levothyroxine (T4) during radio-isotope scanning procedures, since induction of hypothyroidism in those cases is more abrupt and can be of shorter duration. It may also be preferred when impairment of peripheral conversion of T4 and T3 is suspected.

Myxedema Coma — Myxedema coma is usually precipitated in the hypothyroid patient of long-standing by intercurrent illness or drugs such as sedatives and anesthetics and should be considered a medical emergency. Therapy should be directed at the correction of electrolyte disturbances and possible infection besides the administration of thyroid hormones. Corticosteroids should be administered routinely. T4 and T3 may be administered via a nasogastric tube but the preferred route of administration of both hormones is intravenous. Levothyroxine sodium (T4) is given at starting dose of 400 mcg (100 mcg/mL) given rapidly, and is usually well tolerated, even in the elderly. This initial dose is followed by daily supplements of 100 to 200 mcg given intravenously. Normal T4 levels are achieved in 24 hours followed in 3 days by threefold elevation of T3. Oral therapy with thyroid hormone would be resumed as soon as the clinical situation has been stabilized and the patient is able to take oral medication.

Thyroid Cancer — Exogenous thyroid hormone may produce regression of metastases from follicular and papillary carcinoma of the thyroid and is used as ancillary therapy of these conditions with radio-active iodine. TSH should be suppressed to low or undetectable levels. Therefore, larger amounts of thyroid hormone than those used for replacement therapy are required. Medullary carcinoma of the thyroid is usually unresponsive to this therapy.

Thyroid Suppression Therapy — Administration of thyroid hormone in doses higher than those produced physiologically by the gland results in suppression of the production of endogenous hormone. This is the basis for the thyroid suppression test and is used as an aid in the diagnosis of patients with signs of mild hyperthyroidism in whom base line laboratory tests appear normal, or to demonstrate thyroid gland autonomy in patients with Grave’s ophthalmopathy. 131I uptake is determined before and after the administration of the exogenous hormone. A 50 percent or greater suppression of uptake indicates a normal thyroid-pituitary axis and thus rules out thyroid gland autonomy. For adults, the usual suppressive dose of levothyroxine (T4) is 1.56 mcg/kg of body weight per day given for 7 to 10 days. These doses usually yield normal serum T4 and T3 levels and lack of response to TSH. Thyroid hormones should be administered cautiously to patients in whom there is strong suspicion of thyroid gland autonomy, in view of the fact that the exogenous hormone effects will be additive to the endogenous source.

Pediatric Dosage — Pediatric dosage should follow the recommendations summarized in Table 1. In infants with congenital hypothyroidism, therapy with full doses should be instituted as soon as the diagnosis has been made. Recommended Pediatric Dosage for Congenital Hypothyroidism
NP Thyroid Tablets

<table>
<thead>
<tr>
<th>Age</th>
<th>Dose per day</th>
<th>Daily dose per kg of body weight</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 – 6 mos.</td>
<td>15 - 30 mg</td>
<td>4.8 – 6 mg</td>
</tr>
<tr>
<td>6 – 12 mos.</td>
<td>30 – 45 mg</td>
<td>3.6 – 4.8 mg</td>
</tr>
<tr>
<td>1 – 5 yrs</td>
<td>45 – 60 mg</td>
<td>3.0 – 3.6 mg</td>
</tr>
<tr>
<td>6 – 12 yrs</td>
<td>60 – 90 mg</td>
<td>2.4 – 3.0 mg</td>
</tr>
<tr>
<td>Over 12 yrs</td>
<td>Over 90 mg</td>
<td>1.2 – 1.8 mg</td>
</tr>
</tbody>
</table>

HOW SUPPLIED: NP Thyroid tablets (thyroid tablets, USP) are supplied as follows: 30 mg (1/2 gr) are available in bottles of 100 (NDC 42192-329-01), 60 mg (1 gr) are available in bottles of 100 (NDC 42192-330-01), and 90 mg (1 1/2 gr) are available in bottles of 100 (NDC 42192-331-01). NP Thyroid tablets are light tan, round tablets, debossed on one side with “AP” and a 3-digit code on the other side as follows:

- 30 mg (1/2 grain) – “329”
- 60 mg (1 grain) – “330”
- 90 mg (1 1/2 grain) – “331”

Store in a tight container protected from light and moisture. Store between 15°–30°C (59°–86°F).

All prescription substitutions and/or recommendations using this product shall be made subject to state and federal statutes as applicable. Please note: this is not an Orange Book product and has not been subjected to FDA therapeutic equivalency or other equivalency testing. No representation is made as to generic status or bioequivalency. Each person recommending a prescription substitution using this product shall make such recommendations based on each such person’s professional opinion and knowledge, upon evaluating the active ingredients, excipients, inactive ingredients and chemical information provided herein.

BIO-THROID IS AVAILABLE IN:

- .5 Grain
- 1 Grain
- 1.5 Gain

To order contact Nitek at: [www.nitekmedical.com](http://www.nitekmedical.com)
Iodine / Iodide

In the beginning, we evolved from the oceans of the world, where readily available Iodine was an essential part of our composition. As we moved further inland we no longer had a ready supply of Iodine, and we had to obtain it from our food sources. Oceans are a worldwide repository of iodine – very little is in the soil. Dr David Derry Iodine is the one halogen the body requires for many biochemical processes. As soon as the egg and sperm combine, the very first thing that is formed is the Thyroid, the central conductor of all of your hormones and controller of many of the bodies functions. In fact the fetus requires 7 times the amount of Iodine as the mother, and Iodine deficiency predisposes newborns to mental retardation as well as goitre, and lower IQ’s in children living in iodine deficient areas.

In the early 1900’s, governments around the world became aware of the devastating effects of Iodine deficiency, and most governments ordered iodine added to salt, hence Iodized salt, as salt does not contain iodine in its natural form, as salt was the most common commodity that was used universally. However in the past 20 years we all have been advised to cut down on our salt consumption, and many of us have gone to sea salt or designer salts, which only contains microscopic amounts of iodine. Also chloride (salt), along with bromide (Breads) and fluoride (water) are the major halogens, which stop Iodine uptake. Alternatively you could eat copious amounts of seafood, particularly shellfish and seaweed, to bring your iodine levels up, but then there is the question of mercury.

An adequate Iodine level protects the prostate along with the, breasts and ovaries from cancer. Also, iodine contains potent antibacterial, anti-parasitic, antiviral, and anticancer properties. Dr Brownstein suggests one thing to lower your risk of these cancers, it would be to give your patient Iodine/Iodide.

The thyroid cannot function optimally in an iodine deficient state. An Iodine deficient state causes goitre, and may lead to hypothyroidism. Iodine deficiency leads to autoimmune thyroid disorders including Graves and Hashimoto’s disease. Also the white blood cells can’t guard against infection without adequate amounts of iodine. You can’t produce a hormone in the body without iodine.

The Thyroid gland primarily utilizes iodide, while the breasts and prostate primarily utilize iodine. Other tissues like kidneys, spleen, liver, blood, salivary glands and intestine can concentrate either form.

In a normal gland the iodine pump concentrates the iodide to about 30 times the concentration in blood. The rate of trapping is influenced by TSH in a negative feedback control method.

Dr. Brownstein writes: “The illnesses that iodine/iodide has helped are many. These conditions include fibromyalgia, thyroid disorders, chronic fatigue immune deficiency syndrome, autoimmune disorders as well as cancer. Most patients who are deficient in iodine will respond positively to iodine supplementation. In fact, I have come to the conclusion that iodine deficiency sets up the immune system to malfunction which can lead to many of the above disorders developing. Every patient could benefit from a
thorough evaluation of their iodine levels.” In his healthcare practice, he’s found 96 percent of the 5,000 patients tested, are iodine deficient, and that’s a problem!

The information above come from Dr. David Brownstein’s book “Iodine-Why you need it, why you cannot live without it” 4th edition and “Breast Cancer and Iodine: How to Prevent and How to Survive Breast Cancer” by Dr. David Derry M.D., 2006

Iodine/Iodide Guidelines

The optimal daily dosage of Iodine/Iodide is between 12.5 mgs and 50 mgs. (Dr. David Brownstein) Iodine is stored in the body, and it can take nearly a year or (more taking) 12.5 mgs per day to get the body’s levels up to sufficiency.

Iodine/iodide is antibacterial, antiviral, antifungal, anti-parasitic, and anti-inflammatory. Fibrocystic breast disease, breast lumps, cancer and prostate cancer, according to Dr. Brownstein, a person with breast / prostate disease, whose iodine is low, should be stepped up to 50 mgs per day for three months.

We suggest the following: starting at 12.5 mgs/day for week one, titrating to 25 mgs/day for week two, titrating to 37.5mgs / day for week three, then titrating to 50 mgs/day for up to 3 months, or when the patient’s iodine level equilibrates (reaches the normal range), then step down to 37.5 mgs / day for a week then 25mgs / day for the balance of the time. Note that TSH will increase, but once again TSH is not a good indicator of Thyroid function

The autoimmune inflammation response to iodine/iodide deficiency may result in Hashimoto’s and Graves’ disease, as discussed by Dr. Brownstein.

Brownstein believes, that the rise in Hasimotos and Graves disease is attributed to iodine deficiency. With Hasimotos and Graves adequate iodine/iodide must be administered to saturate and iodinate the lipids. As suggested above for breast disease, the patient may have to be titrated up to 50mgs/day. It is important to note that along with the iodine/iodide it may be necessary to address the co-factors Vitamins B2 (riboflavin) and B3 (niacin). According to Dr. G Abraham, 100mgs of B2 and 500 mgs of B3 twice a day will stimulate ATP output. In the management of your patients vitamin C and magnesium are also essential. Selenium is also required in trace amounts.

Once your patient is within the normal range the maintenance dose recommended is 12.5mgs per day. The iodine/iodide should be taken on an empty stomach, at least 4 hours away from any thyroid medications, usually just before the midday meal or the evening meal.

Finally, the major toxic halides that prevents iodine/iodide uptake are Bromine, Chloride & Fluoride, unrefined sea salt (Celtic Salt, can help in the reduction of Bromide), check with your patients for intake of these halides.

The guidelines above come from Dr. David Brownstein’s book “Iodine-Why you need it, why you cannot live without it” 4th edition

The treatments recommended above, are only guidelines. It is your responsibility as a physician to properly monitor your patient with adequate clinical and laboratory screening and management, to achieve your goals with your patient as a skilled practitioner. The above information is a guideline only and no other course of action, whether written or oral is expressed or implied. The interpretation of the data given by the above is the responsibility of you as the practitioner and your practice protocols. Nitek Inc. is not responsible for any erroneous diagnosis or therapy by the practitioner or clinic.
Thyroid Notes

Antibodies Test (TPOab & TGab) = If: (Hypo = 12+, Hyper = 7+), Includes Tachycardia and or Palpitations

Reflex Time: ___________ Ranges: <Hyper = 52 >Hypo = 136, (optimal 52-100) (B/L 120 – 136)
RMR: Will show a reading of about 400 calories below baseline (before treatment) i.e. RMR will be < 1850

Iodine / Iodide Ranges: Saliva 20 to 24 ppm, Urine 10 to 12 ppm Note: do urine test first, on return, test saliva, (saliva & urine - on second test patient must be on 24 hr iodine fast )

If the symptoms scores exceed 8 on the score sheet, the RMR is low, and the Reflex time is slow, the patient has a Thyroid problem, treat according to your protocols.

When a patient is in a Hypo or Hyper state, their heart rate slows down (Hypo) or speeds up (Hyper), the thyroid controls the reflex (Speed) of the heart (the largest reflex muscle in your body) as well as all of your other reflex muscles (points) in your body such as the Achilles, Stapedius, Bracholradialis, in fact in the USA we test the Bracholradialis and in Europe we test the Achilles. In medical school we are all taught that the reflexes speed up and slow down with thyroid function. Before blood testing, the doctors of the day used to treat the patient for suspected thyroid by taking into consideration the patient exhibited, and incorporate the technique of tapping the Achilles, and visually judging the reflex speed to determine a prognosis.

The Thyroflex is 97.5% accurate when compared with FT3 & FT4 (the end artifacts of Thyroid function).

TSH is not a good indicator of Thyroid Function, It does not tell you what the body is converting or using.

If the patient is under a lot of stress, DHEA, VITAMIN D, and CORTISOL are out of range, then consider running an RT3 test.

The treatments recommended above, are only guidelines, It is your responsibility as a physician to properly monitor your patient with adequate clinical and laboratory screening and management, to achieve your goals with your patient as a skilled practitioner. The above information is a guideline only and no other course of action, whether written or oral is expressed or implied. The interpretation of the data given by the above is the responsibility of you as the practitioner and your practice protocols. Nitek Inc. is not responsible for any erroneous diagnosis or therapy by the practitioner or clinic.